

REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicant asserts that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

A. Summary

Claims 1, 4, 12, 71, and 72 have been amended herein. Claims 13-70 were previously canceled. Claims 5-12 and 73-113 are withdrawn as being directed to non-elected species. Therefore, claims 1-12 and 71-113 are currently pending and claims 1-4, 71, and 72 are presently under examination at this time. No new matter has been added.

B. Explanation

It appears that there had been some confusion as to the status of the pending claims, particularly following Applicant's simultaneous election and amendment of November 3, 2009.

Therefore, Applicant wishes to clarify the present status of the claims:

- **Pending claims:** Claims **1-12 and 71-113** are pending in the application.
- **Canceled claims:** Claims **13-70** have been previously canceled.
- **Withdrawn claims:** Claims 2, 5-12, 74-75 and 79-113 have been previously withdrawn, as being directed to non-elected species. However, in the March 4, 2010 Office Action, the Examiner contended that claim 2 should be listed as elected, and claims 73 and 76 as non-elected. Accordingly, the claims currently having a "withdrawn" status are claims **5-12 and 73-113**.

If the Examiner has any objections to the status of claims as it is laid out above, he is respectfully requested to indicate so explicitly, so as to prevent any further confusion.

Claims 1, 4, 12, 71 and 72 have been amended, of which, the amendment to claim 12 is to insert text which was accidentally omitted in the November 3, 2009 response, and the amendment to claims 4 and 71-72 is for clarification purposes. These amendments add no new matter.

Claim Rejections

35 U.S.C. §101 Rejections

In the Office Action, the Examiner rejected claims 1-4 and 71-72 under 35 U.S.C. §101, as being directed to non-statutory subject matter. The Office Action asserts that the claimed invention "does not require the use of technology or transform matter." The Office Action is clearly applying the so-called "machine-or-transformation" test set forth by the Federal Circuit. *See in In re Bilski*, 545 F.3d 943, 954-55. (Fed. Cir. 2008) (*en banc*). Applicant respectfully notes that this decision was overturned by the United States Supreme Court on June 28, 2010. *See Bilski v. Kappos*, 561 U.S. ____ No. 08-964, *slip op.* (2010). The Supreme Court clarified that the "machine-or-transformation test" is no longer the sole test for determining the patentability of method claims under §101. *Id.* Instead, claims are patent ineligible if they are drawn to "abstract ideas."

For clarification, claim 1 has been amended to recite that the "determining" step is performed "automatically", as supported by the specification. Claims 2-4 and 71-72 depend from claim 1. Each of these claims is tied to diagnostic machine(s) and/or devices and none of them is drawn to a merely "abstract idea." For example, claim 1 requires the use of "a labeled marker", which is a well-known, tangible, diagnostic *device*. Moreover, the specification specifically notes that a "gas analyzer" can be used to automatically analyze a subject's breath samples according to the claimed process (including analysis of the levels of the "labeled marker" in claim 1). (Specification at 6).

Finally, to eliminate any doubt that the claimed method complies with § 101, the specification at page 19 explains:

Suitable devices and methods for performing breath tests are described in the above-mentioned U.S. Patent No. 6,186, 958 for "Breath Test Analyzer"; in U.S. Patent Application Serial No. 09/542,768 for "Breath Test Methods **and Apparatus**", and in U.S. Patent Application Serial No. 09/508,805 for "Isotopic **Gas Analyzer**", all assigned to the assignee of the present application, and **all incorporated herein by reference in their entirety.**

(Emphasis added.)

Applicant therefore respectfully requests withdrawal of the § 101 rejection.

35 U.S.C. §112 Rejections

1. In the Office Action, the Examiner rejected claims 71-72 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully traverses this rejection for the reasons set forth below. In the interest of compact prosecution, however, Applicant has amended claims 71-72 to further overcome this rejection.

Claim 71 has been amended and rephrased, so as to more meticulously clarify that "a type of the breath test indicative of the second gastro-intestinal condition is selected based on a result of the breath test indicative of the first gastro-intestinal condition". This method can be observed in the flow chart of Fig. 1B, where different types of breath tests follow one another in sequence.

As to claim 72, the Examiner did not explain the reason for his rejection. Nevertheless, this claim has been voluntarily amended for clarification purposes. It is respectfully asserted that these amendments to claims 71-72 overcome the enablement rejection.

The enablement rejection also fails because the Office Action did not set forth or apply the governing standard. The MPEP explains that enablement rejections which merely recite facts without reference to the eight enablement factors cannot stand. *See* MPEP 2164.01(a); *see also Ex Parte Kopetzki*, 2001 WL 11197754 (Bd. Pat. App. & Interf. 2001). The factors to be considered when determining whether a claim limitation is enabled and whether any necessary experimentation is "undue" include, but are not limited to (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737; MPEP 2164.01(a). It is improper to conclude that disclosure is not enabling based on an analysis of only one of the factors while ignoring one or more of the others. *See, e.g. Ex parte Noguchi*, 2002 WL 1801470 (Bd. Pat. App. & Interf. 2001).

Here, the Office Action does not mention or apply any of the eight enablement factors and relies solely on a conclusory assertion of non-enablement. Yet mere conclusory statements are not sufficient to sustain an enablement rejection under Section 112. *See In re Brebner*, 455 F.2d 1402 (CCPA 1972). Moreover, the Patent Office is required to assume that the specification is enabled.

See *IN re Marzocchi*, 439 F.2d 220 (CCPA 1979). The Examiner must put forth sufficient reasons supported by the record as a whole (and applying the eight factors set forth above) as to why the specification is not enabling. Then, and only then, does the burden shift to Applicant to show that the specification is enabling. See MPEP 2164.04.

Applicant has clearly set forth the claimed methods in claims 71-72 in a manner which readily enables one of ordinary skill in the art to make and use the invention. The flow chart on Figure 1(b), read in conjunction with the supporting specification, sets forth a detailed, step-by-step method of selecting a second breath test based on the results of the first test. Each test is clearly labeled in the flow chart and described in the specification. Indeed, "the amount of direction provided by the inventor" (enablement factor #6) could scarcely be higher.

The burden therefore remains on the Examiner to put forth a *prima facie* case of non-enablement. Applicant respectfully requests withdrawal of this § 112 rejection.

2. The Office Action also rejected claims 4 and 71 under 35 U.S.C. §112, second paragraph, as being indefinite.

Claim 4 has been amended according to the Examiner's suggestion to clarify that the condition referred to is indeed a "gastric emptying disorder".

Claim 71 has been amended and rephrased as described in (1.), above. As amended, claim 71 no longer includes the term "evaluation" (for which the Office Action asserted there was no antecedent basis).

As amended, claims 4 and 71 are no longer indefinite. Applicant therefore respectfully requests withdrawal of the rejections based on Section 112.

35 U.S.C. §103 Rejections

Initially, Applicant wishes to thank the Examiner for acknowledging that the current claims are entitled to the filing date of the provisional application, namely, August 23, 2001.

In the Office Action, the Examiner rejected claims 1-4 under 35 U.S.C. §103(a), as being unpatentable over Wagner et al. (US 6,548,043). Applicant respectfully traverses these rejections in light of the arguments that follow.

Wagner, as the Office Action explains, recites a test wherein: a meal is administered to a person with a labeled marker; a breath test is performed; and a gastric emptying disorder is identified based on the breath test. (Office Action at 4). The Office Action readily concedes that Wagner fails to disclose or claim a method for diagnosing a **second** gastro-intestinal condition. *Id.* Nevertheless, the Office Action rejects claims 1-4 based on the conclusory assertion that "it is standard medical practice for a physician to diagnose all conditions a patient presents with." *Id.*

Applicant respectfully disagrees with the Office Action's analysis and conclusion, which are based on a misreading and misapplication of Wagner. If a physician were to use Wagner's method in order to fully diagnose a patient suffering from two (or more) gastro-intestinal conditions, he or she will have to administer a test meal, perform a breath test, diagnose the first condition, and then administer another test meal, perform another breath test and diagnose the second condition. This is because Wagner **does not** disclose, teach or suggest a method in which, as in claim 1, **both** the first and the second gastro-intestinal conditions are determined following administration of **one** meal. In other words, the method disclosed and claimed in Wagner *cannot* be used to carry out the presently claimed invention. Likewise, the combination of successive Wagner tests will also fail to yield the method recited in claim 1 – which allows automatic diagnosis of two (or more) gastro-intestinal conditions following the administration of a single test meal.

In its only independent claim (claim 1), Wagner recites a method of measuring delayed gastric emptying "consisting of" of several steps. Those steps include administering a "test meal" to a patient and subsequently "determining" the "gastric emptying of the patient" based on the results of a gastric emptying breath test. Col. 11:10-27. **Use of the transitional phrase "consisting of" excludes any element or step not specified in the claim.** See *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); see also *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) and MPEP 2111.03. Thus, according to its own claimed limitations, Wagner's method specifically excludes the determination of two or more gastro-intestinal conditions. Indeed, the Office Action concedes this point on page 4. ("[the method of Wagner] does not diagnose second gastro-intestinal condition.") A cited reference must be considered for all that it teaches, including disclosures that "teach away" from the present invention. See *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281 (Fed. Cir. 1985). As explained above, Wagner's

only independent claim teaches away from the presently claimed method (requiring diagnosis of *two or more gastro-intestinal conditions* following administration of a single test meal).

Furthermore, it is well-settled law that obvious rejections cannot be based on proposed modifications (or combinations) which alter the principle or purpose of a prior art reference. See *In re Ratti*, 270 F.2d 810 (CCPA 1959); and *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984). Yet the rejection of claims 1-4 under Section 103 is based on just such a modification (and/or combination). The *purpose* of Wagner is to diagnose a *single* gastro-intestinal disorder based on an explicit set of principles (or process steps) in claim 1. Claims 1-4, however, recite a process for diagnosing *two or more* gastro-intestinal conditions based on a different set of principles (or process steps). In order to reject claims 1-4 as obvious, the Office Action proposes to "change the principle of operation [of Wagner's claimed method]". See *In re Ratti*, 270 F.2d at 810. Any such modification (or combination), however, is insufficient to render the claims *prima facie* obvious. *Id.*; see also MPEP 2143.01.

Consequently, the Office Action's conclusory statement that "it would have been obvious to diagnose both conditions" proceeds from an improper factual and analytical basis. The § 103 rejection should therefore be withdrawn. Applicant wishes to further emphasize that such an argument as to obviousness cannot be reasonably made even based on the Applicant's understanding of Wagner (as explained above) in combination with standard medical practice and knowledge. This, since a person of ordinary skill in the art, even if he "is also a person of ordinary creativity" (*KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007)), would not have been able to devise the method of claim 1, in which **both** the first and the second gastro-intestinal conditions are determined following administration of **one** meal, based solely on the application of standard medical practice and knowledge to Wagner's method.

Accordingly, it is respectfully requested that the §103(a) rejection of claim 1 and claims 2-4 which depend from it be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objections and rejections and pass this application to issue. If there are any questions, the Examiner is invited to call Applicant's representative Rodney Fuller at (602) 916-5404 to resolve any remaining issues to expedite the allowance of this application.

Respectfully submitted,

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Date

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